GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4946
ANSWERED ON:31.03.2017
Bio-technics
Chandel Kunwar Pushpendra Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has formulated any policy to promote the medicines manufactured through bio-technics and if so, the details thereof;

(b) whether the Government has analysed the adverse effects of the use of these medicines;

(c) whether the Government has constituted a specialist team to assess the impact of the use of the said medicines on the supply of generic medicines; and

(d) if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a): The medicines manufactured through bio-technics (i.e. Bio pharmaceuticals, Similar Biologics, etc.,) are regulated as per provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945 and Rules for manufacture, use, import, export and storage of hazardous micro-organisms/ genetically engineered organisms or cells, 1989 notified under the Environment (Protection) Act, 1986. Further, a document titled "Guidelines on Similar Biologics: Regulatory requirements for marketing authorization in India" have also been prepared and placed in public domain. These guidelines clearly indicate data requirements for molecular biology, production, purification, quality attributes, bio-efficacy and stability studies in respect of biosimilars.

(b): No drug is 100% safe. Therefore, all drugs are approved and allowed to be manufactured and marketed in India based on their risk-benefit analysis.

(c): No.

(d): Does not arise.